AUG 2 0 2002

K013759

510(k) SUMMARY

NEEDLESCOPE
(MSS-28CS-301/701)
and
SCOPE CONNECTING ADAPTER FOR MICROSCOPE
(MAJ-943)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	8010047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5177 FAX 81-426-46-5613

2. Name of Contact Person

Name :	Ms.Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157
Address, Phone and Fax :	TEL (631)844-5688 FAX (631) 844-5416

B. Device Name, Common Name

1. Device Name :	MSS-28CS-301/701 NEEDLESCOPE
2. Common/Usual Name :	NEEDLESCOPE
3. Classification Name :	Neurological endoscope 21CFR882.1480

C. Predicate Devices:

Model	Device Description & 510(k)#/ Date Cleared	Manufacturer
Neuro Endoscope	#K973140 07/29/1998	Olympus Optical Co.,
MaCHIDA FLEXIBLE NEURO-ENDSCOPE NEU-4/4L	#K993568 03/13/2000	MACHIDA ENDOSCOPE CO., LTD.

D. Description of the Device

This instrument has been designed to be used with the OPERATION MICROSCOPE OME-8000 for use in observation of the brain ventricles and the brain parenchyma, in confirmation of clips on cerebral aneurysms, and for diagnostic procedures, such as observation of cerebral aneurysms, observation of cerebral tissues including brain tumors, observation of cerebral vascular systems and cranial nerves, and observation of hypophysis tumors.

This Instruments are two types (MSS-28CS-301/701) of NEEDLESCOPE used with OPERATION MICROSCOPE OME-8000 which is 510(k) exemption device, and SCOPE CONNECTING ADAPTER FOR MICROSCOPE (MAJ-943) which Intervenes between the NEEDLESCPE and the OME-8000.

1. NEEDLESCOPE (MSS-28CS-301/701)
   This device is used with the OPERATION MICROSCOPE OME-8000 for observing the brain ventricles and the brain parenchyma and for performing diagnostic procedures.

2. SCOPE CONNECTING ADAPTER FOR MICROSCOPE (MAJ-943)
   This device is for connecting the NEEDLESCOPE and OPERATION MICROSCOPE OME-8000.

E. Intended Use of the device

This instrument has been designed to be combined with the OPERATION MICROSCOPE OME-8000 for use in observation of the brain ventricles and the brain parenchyma, in confirmation of clips on cerebral aneurysms, and for diagnostic procedures, such as observation of cerebral aneurysms, observation of cerebral tissues including brain tumors, observation of cerebral vascular systems and cranial nerves, and observation of hypophysis tumors.

F. Reason for not requiring clinical data

The application to the brain ventricles is the same as the predicate device OLTMPUS NEURO ENDOSCOPE A7595.
And also it is apparent by literatures that the application of this kind of device to the brain parenchyma is usual.
As the result of evaluating the thermal influence by Cow's brain to the brain ventricles and parenchyma by illumination light coming from the distal end of NEEDLESCOPE, there was no visible change on the surface and inside of the brain.
Olympus has determined that clinical data is not required, since the Needlescope MSS-28CS-301/701 does not contain any significant changes in the Intended use, method of operation, materials or design that could affect the safety or effectiveness of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2002

Olympus Optical Company, LTD.
c/o Laura Storms-Tyler
Olympus America, Incorporated
Two Corporate Center Drive
Melville, New York 11747 - 3157

Re: K013759
Trade/Device Name: MSS-28CS-301/701 Needlescope
Regulation Number: 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: May 21, 2002
Received: May 22, 2002

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013759

Device Name: NEEDLESCOPE MSS-28CS-301/701

Indications for Use:

OLYMPUS NEEDLESCOPE MSS-28CS-301/701 has been designed to be combined with the OPERATION MICROSCOPE OME-8000 for use in observation of the brain ventricles and the brain parenchyma, in confirmation of clips on cerebral aneurysms, and for performing diagnostic procedures, such as observation of cerebral aneurysms, observation of cerebral tissues including brain tumors, observation of cerebral vascular systems and cranial nerves, and observation of hypophysis tumors.

for Mark N. Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013759

Concurrence of CDRH, Office of Device Evaluation ODE

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 876.4400)

(Optional Format 1-2-96)